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13. ABSTRACT ***(Maximum 200 Words)***

An average of three months rest is generally recommended for resolution of tibial stress fractures. Such an extended absence from athletic or military training reduces the ability to perform optimally and the likelihood of successful return to activity upon recovery.

Electric field stimulation has been shown to accelerate bone healing. While there is reason to believe that this effect will extend to the healing of stress fractures, no rigorous investigations of this application have been performed. We are collecting data in order to compare recovery times from tibial stress fracture in male and female subjects treated with either active or placebo-control electric field stimulation.

There is an associated need to establish a cost effective, reliable method of diagnostic imaging for tibial stress fractures. Four forms of diagnostic imaging (radiographs, bone scan, MRI and CT) are performed on each subject. The films will be evaluated according to the ability of each to identify tibial stress fractures and predict time to healing. Establishment of a stress fracture severity grading system for each imaging technique will facilitate predictions of recovery times with and without electric field stimulation according to degree of injury.

We have collected data from seven subjects in Year 1, however, due to the nature of the study design, we are unable to report findings until the conclusion of the investigation when the devices will be unblinded. Further, to maximize intra-evaluator reliability, reading and grading of all films should occur simultaneously, thus no imaging evaluation will occur until data collection is complete.

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FOREWORD

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Introduction

The primary research goal of the study *Do capacitively coupled electric fields accelerate tibial stress fracture healing?* is to establish the efficacy of a novel bone stimulator device for stress fracture indications. Electric or electromagnetic fields have been shown to stimulate osteogenesis (1-11) following non-union fracture and bone graft, however, the application to stress fractures has been poorly studied. Our study is designed to fill this research oversight for the purposes of discerning if electric field stimulation can accelerate tibial stress fracture healing, thereby reducing time away from training for athletes and military recruits. Secondarily, we are collecting data on four methods of stress fracture imaging (x ray, nuclear medicine, MRI, CT) for the purposes of refining severity grading systems, comparing sensitivity and specificity, as well as the ability of each technique to predict time to healing.

Body

Our original Statement of Work explained that a convenience sample based on flow of tibial stress fracture cases at local Sports Medicine Clinics would be utilized, thus no exact statement of work timeline could be provided. It was predicted that some periods of the year would produce more subjects than others, according to the seasonal nature of athletic events associated with high incidence of tibial stress fracture, and this had indeed been found to be the case.

The preliminary study activities, described as; 1. meetings and discussion with Sports Medicine Clinic physicians, and 2. purchasing supplies, were completed initially. Contact was made via mailings and telephone calls and followed up by office visits to local Sports Medicine orthopedists. We also contacted head Athletic Trainers at surrounding Community Colleges (Canada College, DeAnza College and Foothill College), contacted the Leukemia Society Team in Training organization for potential referrals, posted advertising flyers in local running shoe stores and continue to hand out flyers at community running events. We are currently working predominantly with the Stanford University track team physician (Dr. Mike Fredericson) and a podiatrist at the Palo Alto Medical Foundation (Amol Saxena) for referrals, having obtained most of our study subjects from these two sources. Biolectron Inc., the company providing the OrthoPak™ devices, has been very helpful in providing devices in a timely manner and assuming responsibility for blinding the active and control units.

Specific Year 1 goals were to: 1. interact with Sports Medicine Clinicians and Radiologists to establish standards of evaluation, 2. purchase supplies, 3. recruit and treat ~ 16 subjects, and 4. analyze images. Items 1 and 2 have been addressed.

Although we predicted that we would recruit approximately 16 subjects in the first year, we have completed data collection on only 7 subjects at the present time. This shortfall may be due in part to the placebo controlled nature of the trial. Patients at referral clinics often prefer to be treated with a bone stimulating device at their own expense, rather than to participate in a trial where there is a 50% chance of receiving an inactive device. These problems are not insurmountable, however, as free imaging along with a complimentary bone density evaluation offered at the Musculoskeletal Research Laboratory have been motivating influences for

participating subjects.

All films are currently in the hands of the study radiologist (Bergman), but are, as yet, unevaluated. It was agreed that for the most rigorous and consistent analysis, all images should be evaluated simultaneously and by multiple reviewers. For this reason, all films will remain stored until the study conclusion at which time three radiologists will independently review and grade the five sets of films for each subject.

Ongoing activities outlined in the Statement of Work continue to be completed per the study protocol.

Key Research Accomplishments

No findings to report until study is unblinded on its conclusion.

Reportable Outcomes

SUBJECT #	SEX	AGE	PRIMARY SPORT	*TREATMENT TIME (days)*
1	Female	32	Running	18
2	Male	35	Running	19
3	Female	46	Running	23
4	Female	16	Running	25
5	Male	30	Running	14
6	Male	22	Running	14
7	Male	18	Running	21

Conclusions

A summary of results cannot be provided until study is unblinded. No protocol changes are recommended.

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Appendices

N/A